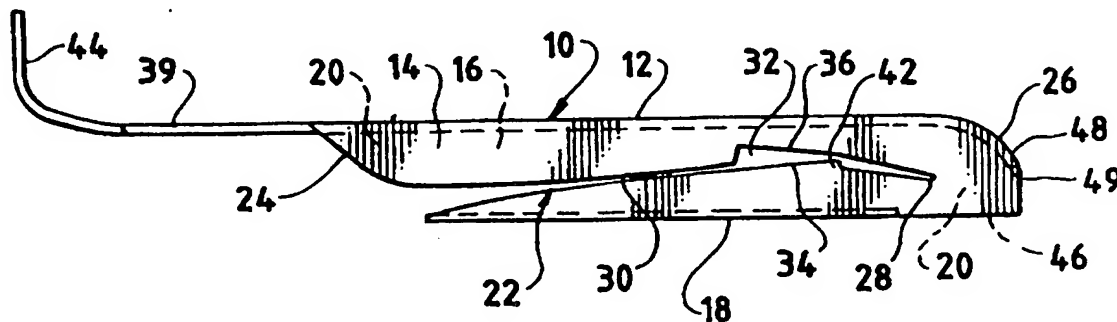




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<b>(21) International Application Number:</b> PCT/US96/20740 <b>(22) International Filing Date:</b> 20 December 1996 (20.12.96)  <b>(30) Priority Data:</b> 08/584,451           11 January 1996 (11.01.96)   US 08/714,959           17 September 1996 (17.09.96)   US  <b>(71) Applicant:</b> MEDISYSTEMS TECHNOLOGY CORPORATION [US/US]; Suite 1100, Bank of America Plaza, 300 South Fourth Street, Las Vegas, NV 99101 (US).  <b>(72) Inventor:</b> UTTERBERG, David, S.; 2033 First Avenue, No. 3, Seattle, WA 98121 (US).  <b>(74) Agent:</b> ELLIS, Garrettson; Gerstman, Ellis & McMillin, Ltd., Suite 2010, 2 N. LaSalle Street, Chicago, IL 60602 (US).		<b>(81) Designated States:</b> AU, CA, JP, KR, MX, NO, NZ, European patent (AT, BE, CH, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE).  <b>Published</b> <i>With international search report.</i>

**(54) Title:** EASY USE NEEDLE PROTECTOR SHEATH



**(57) Abstract**

A medical needle protector sheath (10) which comprises a body having a top wall (12), side walls (14, 16), an open first end (24), and slots (22) formed in each side wall to receive a needle wing extending through each of the slots. The slots extend from the first end toward a second sheath end (26) opposed to the first end, with the slots terminating in the side walls at end points which are spaced from the second end. Typically, first portions (40) of the slots adjacent to the end point slope away from the top wall as the slots extend toward the second end. Other portions (30) of the slots slope toward the top wall as the slots extend to the second end (26). Various improvements are described which result in safer and easier use of the needle protector sheath.

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## EASY USE NEEDLE PROTECTOR SHEATH

TECHNICAL FIELD

Many types of needle protector sheaths are known. Particularly, needle protector sheaths for winged needles are presently in clinical use, in which the wings of the needle project outwardly through slits defined in the sheath, so that the sheath can slide from a retracted position while the needle is in use to an advanced positioned in which the needle is enclosed, the sheath being locked in that position so that the point of the needle is recessed in the sheath and cannot cause accidental injury. For examples of such devices, see Utterberg et al. U.S. Patent No. 5,112,311; Shields U.S. Patent No. 5,350,368; Gollobin et al. U.S. Patent No. 5,330,438; Masters et al. U.S. Patent No. 4,941,881; Japanese Patent Publication 1-212,561; and Fayngold U.S. Patent No. 5,120,320 among others.

As one disadvantage of such protector sheaths for needles, since they carry a slit it is at least remotely possible for the needle to rotate in a horizontal manner after it has been placed in the sheath, causing the needle tip to project laterally out of one of the slits, where it may cause accidental injury.

As another issue, the clinicians who use the needle protector sheaths wish to make sure that the wings of the needles are securely latched into a rear end portion of the slots as the sheath is advanced, so that the sheath will not accidentally retract, again exposing the needle. With earlier designs, some difficulties have been encountered in easily moving the needle and wings into a retracted, latched position where the needle tip is securely recessed, while at the

same time assuring that the point of the needle is securely retained within the sheath in a position where it cannot shift and project laterally outwardly through one of the slots.

5 By this invention, improvements are provided to medical needle protector sheaths to give greater assurance that the sheath and needle are locked together after needle use, with the needle being reliably positioned in retracted position within the sheath, so  
10 that any possible accidental failure resulting in the needle projecting out of the sheath again is eliminated.

Particularly, one can easily move the needle and wings into a retracted, latched position where the needle tip is securely recessed, while at the same time  
15 assuring that the point of the needle is securely retained within the sheath in a position where it cannot shift and project laterally outwardly through one of the slots.

Furthermore, in the use of fistula needles for  
20 hemodialysis and the like, some nurses insert the needle into a patient with the bevelled tip of the needle end facing up, and some insert the needle with the bevelled tip down. In many of the prior art needle guards, this can significantly affect the utility of the guard in  
25 catching and holding the needle as it is withdrawn from the patient in the customary manner. Most current fistula needle wings project from their hub from a position that is laterally spaced from the center line defining the needle axis. Thus, with many of the prior  
30 art slotted needle guards, if a needle has been inserted into a patient with a bevelled needle point up, the wing may pass through the slots of the guard with most of the

needle and hub being positioned above the slots (when viewed from the side). However, if the same needle is inserted into a patient with the bevelled needle tip down, then the needle and hub will be positioned mostly  
5 below the slot. In each case, of course, the wings will occupy the slot, but the positioning of the rest of the needle and the hub may be substantially changed.

Thus, many of the slotted needle guards of the prior art work poorly for needles and hubs that have  
10 been inserted into the patient in an "upside down" manner, from the viewpoint of the design of the prior art slotted guard.

If many of the prior art needle guard sheath configurations were made of a deformable plastic so as  
15 to be forgiving as to differences in the dimensions of winged needles, (and particularly the difference in dimensions between a winged needle and the same winged needle in an inverted position) the same flexibility of the sheath housing creates the risk that the prior art  
20 catches used to hold the wings of the needle in a retracted position in the sheath may accidentally release the wings through flexing of the housing. Thus, any prior art units that were deformable exhibited a safety problem in that the needle and wings of the  
25 winged needle could be accidentally released.

By this invention, a new type of catch is provided, which is more forgiving to flexing of the medical needle protector sheath of this invention, and which more reliably holds the wings of needles, thus  
30 preventing them from being accidentally removed from the sheath or accidentally allowing the needle point to project laterally outward through the slots.

Furthermore, the prior art needle sheaths often utilize an "anchor" as typically taught in Utterberg et al. U.S. Patent No. 5,112,311. In the field of dialysis, when a winged fistula needle is to be removed, the nurse presses the site of needle entry with a wad of gauze, while bringing the needle sheath up to a position where one of her fingers can press on or otherwise grasp the forwardly projecting "anchor". Then, the nurse pulls the needle tubing, causing the needle to withdraw and to retract back into locked relation with the slotted sheath, while the sheath is prevented from retraction by the manual pressure on the anchor. At this moment, the nurse does not want to reduce finger pressure on the gauze, which is preventing bleeding at the needle access point. In the prior art, this means that the nurse cannot conveniently release the anchor so that the needle and set can be removed without a reduction in finger pressure.

By this invention, the advantages of an anchor on the slotted sheath may be achieved, but at the same time the sheath and needle may be removed without the nurse letting up on the finger pressure on the gauze.

Furthermore, the protector sheath of this invention holds the needle in a locked relation in which the needle extends upwardly into substantial engagement with the top wall of the sheath. This puts the tip of the needle in vertically spaced relation to the slots in the sidewalls, providing further assurance that the needle tip cannot project out of a sidewall. This can be facilitated by the use of an end wall which extends downwardly part of the distance from the top wall toward a bottom wall of the sheath, forcing the needle hub and

tubing downwardly, rather in a pivoting relation about the wings in slot portions of the sheath, which, in turn, forces and holds the needle tip up.

5

#### DESCRIPTION OF THE INVENTION

By this invention, a medical needle protector sheath comprises a body having a top wall, side walls, an open first end, and a slot formed in each side wall to receive a needle wing extending through each of the  
10 slots. The slots extend from the first end toward a second end opposed to the first end, with the slots terminating in the side walls at closed end points which are spaced from the second end.

In one embodiment, first portions of the slots  
15 are positioned adjacent to the end points, the first slot portions sloping away from the top wall as the slots extend toward the second end.

The protector sheath further preferably comprises a bottom wall which is connected to the side walls. The  
20 bottom wall may be spaced inwardly from the second end of the sheath to define a recess. This can permit a needle and hub positioned in the sheath, particularly with the needle wings positioned in the first, sloping slot portions, to be tilted so that the needle tip  
25 preferably engages and can dig into the top wall. As this takes place, the hub may occupy at least some of the recess defined by the inward spacing of the bottom wall.

It is also preferred for an end wall to be  
30 defined at the second end of the sheath. This end wall extends from the vicinity of the top wall, and is preferably integral therewith. The end wall may define

a smooth, downwardly extending curve from the top wall, or may be of another shape, extending downwardly to a position above the bottom wall to provide room for the needle hub and connected tubing to extend out of the second end of the sheath. The end wall firmly holds and constrains the needle and hub in a desired acute angle to the top wall, which acute angle may correspond to a lesser or equal angle of the first portions of the slots. Typically, the needle hub or its tubing may abut the lower edge of the end wall, which prevents it from being raised or rotated about its wings to put the needle and hub into a more parallel relation with the protector sheath. At the same time, the needle and hub may be constrained against rotation in the other direction by the impinging of the needle or its tip against the top wall of the sheath. Thus, the needle and hub may not only be retained in firm, non-moving relation to the sheath by conventional first catch projections defined in the first portions of the slots, but it can be held against rotation relative to the sheath by the points of impingement at the bottom of the end wall and between the needle point and the top wall.

It is also preferred for the slots to define second portions, which are positioned adjacent to the first slot portions but nearer to the first end than the first slot portions. These optional second slot portions define a greater slot width than other slot portions, to permit a degree of free vertical rotation of the wings of a medical needle which occupy the second slot portion. Thus, while the needle occupies the second slot portion, it can rotate with ease through a certain, constrained angle. This is particularly



advantageous when, as is preferred, most of the parts of the slots positioned between the first slot portion and the first sheath end slope toward the top wall as the slots extend towards the second end. Such a slot shape without the second portions is taught in the Utterberg U.S. Patent Nos. 5,562,636 and 5,562,637.

Since the respective slots first extend upwardly toward the top wall, and then curve downwardly again away from the top wall, the needle and hub must rotate as their wings slide along the slots, when the needle is being retracted into the sheath. The second portions of the slots, permitting a degree of free rotation of the needle, facilitate the retraction process, reducing the force necessary to bring the sheath and needle together into latched relationship.

It is also preferred for an upstanding handle for manual retention of the sheath to project from the top wall at or near the first end of the sheath. This provides a better grip on the sheath than has been previously provided, so that the needle may be pulled from its position within the patient by pulling the connected tube, causing the needle to retract to slide along the slots, and to latch into position with a discernable snap. This indicates reliable latching of the sheath in protective position around the needle. While one finger holds the upstanding handle, other fingers of the user may press overlying gauze (as generally described in the previously cited Utterberg U.S. Patent No. 5,112,311) to suppress bleeding after needle removal in conventional manner.

If desired, the upstanding handle may be a finger ring. The handle may be defined on a forward extension

of the top wall which extends forwardly beyond the side walls at the first end.

It also may be desirable for the top wall of the sheath to define an elevated portion adjacent to the first end, which correspondingly provides an elevated space inside the sheath. This permits use of the sheath with longer needles, providing a broader range of needle lengths with which a single protector sheath may be used.

In another embodiment, the sidewalls define at least one catch projection which is spaced from the closed ends of the slots, to prevent needle wings that occupy the first slot portions from easily sliding away from the first slot portions. The catch projection defines an elongated member having a first end that defines a wing catching tip extending into one of the slots. The elongated member is attached to the sidewall only at an elongated member end that is opposed to the first end, to permit the elongated member to flex in the sidewall plane. Also, the elongated member preferably extends into a direction that defines an acute angle to at least the majority of the top wall, with the first end facing the first slot portion.

Preferably, the wing catching tip of the elongated member is either in contact with the upper surface of the slot or in close proximity thereto. Particularly, it is preferred for the elongated member to be spaced, in its normal, unflexed position, from the slot upper edge by a distance which is less than the thickness of the needle wings that the sheath is designed to retain.

Preferably, the first slot portions extend at an

acute angle away from the top wall from the vicinity of the elongated members to the closed slot ends.

As before, the sheath may further comprise a bottom wall, and an end wall at the one body end which is adjacent to the slot closed end portions. The end wall extends from the vicinity of the top wall downwardly to a position above the bottom wall, if present or otherwise above the bottoms of the sidewalls, so that, as a result of this, the needle and hub may be held in the sheath at an acute angle to the top wall when the wings occupy the first slot portions.

Also, portions of the slots which are more remotely spaced from the end wall than the elongated member may extend from the vicinity of the elongated member in an acute angle away from the top wall to open slot ends at the needle protector sheath end which is opposed to the one end.

The sheath may also have a flexible, upstanding handle which is preferably of C-shape, for manual retention of the sheath. This handle may project from the top wall adjacent the end of the sheath which is opposed to the one end. Also, the handle may communicate with the top wall of the sheath through a line of flexing weakness, to facilitate the flexibility of the handle. Thus the user, while withdrawing a winged needle into the sheath, may hold the upstanding handle with a finger. The handle may have sufficient stiffness to permit the needle to be pulled into the sheath and locked therein, but the handle is sufficiently flexible so that the sheath may be removed from the finger that the handle engages by flexing without a need to move the finger.

The sheath may also be made of a flexible plastic so that it can receive and hold winged needles of a variety of shape configurations, which includes, as previously discussed, needles which are of differing dimension relative to the plane of the wings, when  
5 inverted. Also, the elongated member may carry a longitudinal strengthening rib.

By the use of the above features either together in various combinations or separately, significant  
10 advantages may be achieved in the use and handling of winged needle protector sheaths.

#### DESCRIPTION OF THE DRAWINGS

In the drawings, Fig. 1 is an elevational view of  
15 a first embodiment of the needle sheath of this invention;

Fig. 2 is an elevational view of a second embodiment of the needle sheath of this invention, showing a needle carried therein;

20 Fig. 3 is an end elevational view of the needle sheath of Fig. 1 and Fig. 2;

Fig. 4 is a bottom plan view of the needle sheath of Fig. 1 and Fig. 2;

Fig. 5 is a side elevational view of a third  
25 embodiment of the needle sheath of this invention;

Fig. 6 is a side elevational view of a fourth embodiment of the needle sheath of this invention;

Fig. 7 is a perspective view of a needle sheath of this invention, carried on a fistula set for  
30 hemodialysis;

Fig. 8 is an enlarged elevational view of the first or back end of the sheath, showing how a wing of

the needle, shown in section, can move to the first slot portion adjacent the one end of the body; and

Fig. 9 is an enlarged elevational view of the complete protector sheath, showing how the wing of the  
5 needle is held in position within the first slot portion by the catch projection;

#### DESCRIPTION OF SPECIFIC EMBODIMENTS

Referring to the drawings, Fig. 1-6, shows a  
10 hollow needle sheath 10 which has a top wall 12, side walls 14, 16, and a bottom wall 18, being positioned in rectangular array in a manner similar to that shown in Fig. 3. Needle sheath 10 also defines an inner bore or lumen 20 of generally rectangular shape, being at least  
15 partially open at each end.

Sheath 10 also defines slots 22 extending through first end 24 of the sheath and extending toward second end 26. Each of slots 22 are of substantially identical shape and terminate at respective end points 28 at a  
20 position spaced from second end 26.

As shown in Fig. 2, sheath 10 may be threaded on a winged needle which is connected to a tube in conventional manner. The needle may be originally positioned in the venous system of a patient. Thus,  
25 when the needle is withdrawn, it slides to the rear, with the wings entering slots 22 or 22a. Initially the needle is angled slightly upwardly as it occupies the skin of the patient, similar to that shown in Fig. 14 of Utterberg Patent No. 5,112,311, at an angle  
30 approximately parallel to the forward section 30 of slot 22 as it rests on the skin of the patient. Thus, as the needle is pulled backwards out of the patient, it slides

diagonally upwardly along forward slot sections 30, 30a in a manner that minimizes twisting and bending of the needle while the needle tip remains in the patient.

Then, the wings of the needle enter a second slot  
5 section 32, 32a as defined above, which is of increased width relative to other portions of the slots 22. Because of this increased width, the needle wings are free to rotate out of connection, for example, with the lower edge 34 of slot section 32 into engagement with  
10 upper edge 36 of second slot section 32, causing the needle to rotate in clockwise manner into a position similar to that shown in Fig. 2. Fig. 2 shows a needle sheath similar in its basic construction to that of Fig. 1 except for the construction of upstanding handle 44,  
15 44a, carried on a forward extension 39, 38 of upper wall 12, 12a.

The needle is pulled backwards into snap-fit relation with a first section 40, 40a of the slots, which section carries a generally conventional catch  
20 projection 42, 42a for retention of the wings in the respective first slot sections 40, 40a. The presence of the widened second slot section 32, 32a permits the spontaneous rotation and the easy transition of the needle and wings to a different angle as the needle is  
25 drawn backwards into sheath 10 and into locking relation therewith in first slot section 40. Thus, the necessary pulling force to accomplish this is reduced.

Upstanding handle 44 of Fig. 1 simply represents an upwardly turned projection which may be retained by  
30 the finger of the user's hand. Typically with the same hand, the user is covering the needle injection site of the patient with gauze pads. Thus, one can remove the

needle from the patient by pulling the hub or its connected tubing 58, causing the needle to retract into the sheath. As this is done, one can firmly hold handle 44, 44a of the sheath with one finger to prevent it from retreating with the needle.

In Fig. 2, the upstanding handle 44a may be a hollow tube or a ring, preferably of approximately the width of sheath 10a as shown in Fig. 4. The various reference numerals of Figs. 2 and 4 which end with suffix "a" correspond to the parts referred above by the corresponding numbers of Figs. 1 and 3 without the suffix. For example, bottom wall 18a of Figs. 2 and 4 correspond to bottom wall 18 of the Fig. 1 embodiment.

Both of the embodiments of Figs. 1 and 2 define a bottom wall 18, 18a which are connected to the side walls, but are spaced inwardly from the second end 26, 26a to form an optional recess 46, 46a. Coupled with this, it is preferred for an end wall 48, 48a to connect with the top wall 12, 12a and to curve downwardly from the top wall to a bottom position 49 above bottom wall 18, 18a that permits winged needle and hub assembly 50 to extend into the bore 20 underneath end walls 48, 48a. Typically, as shown in Fig. 2, the wings 52 of assembly 50 are held in an angle to the longitudinal axis of sheath 10, 10a as they occupy first portion 40, 40a of the slots, which first portion occupies a similar angle. The presence of end wall 48 prevents assembly 50 from rotating upwardly by flexing wings 52, because such counterclockwise rotational motion is prevented by the abutment of assembly 50 against the lower edge of end wall 48 or 48a. However, needle and hub 50 does not have to abut end wall 48. It may be spaced from it.

Also, in the fully retracted, locked configuration of needle assembly 50 as shown in Fig. 2, the upwardly angled needle point 56 preferably presses against top wall 12a, being directed there by the angle and position of slot portions 40a and the position of the lower edge of end wall 48a. Thus, needle tip 56 presses against top wall 12, 12a when in its fully retracted and locked position, with the wings being locked in generally conventional manner in first slot portion 40a. This also prevents needle assembly 50 from rotating in clockwise manner around the flexible wings, so that the needle assembly is rigidly affixed within sheath 10a, being incapable of rotation about the flexible wings 52 because of the engagement at the lower edge of end wall 54 and at the point of engagement of needle tip 56 against the undersurface of top wall 12a.

The aperture 46a in the bottom wall makes it possible for needle assembly 50 to project slightly below the side walls as necessary to achieve this configuration. Also, if desired, the wall that defines aperture 46a may serve as a secondary catch for the annular face of the tubing 58 to which the needle is attached.

Similar relationships may be applied between a winged needle hub and the Fig. 1 embodiment.

Referring to Fig. 5, another embodiment of the sheath of this invention is disclosed. Sheath 10b can be of identical structure to that of the previous designs except as otherwise described herein. The difference lies near the first end of sheath 10b, while slot 22b and most of the length of the respective walls can be identical to the above.



It can be seen that on the left side of the sheath of Fig. 5, the extension of top wall 38, 39 has been eliminated, and a different, upstanding handle 60 is provided in the form of a finger ring which attaches to top wall 12b at two different places 62, 64. Also, top wall 12b defines an externally and internally elevated portion 66, which allows longer needles 56a or shorter needles to be retained in the same guard, with their respective wings 52a sliding along the slot 22b into first slot portion 40b with substantially the same catchment angle as shorter needles. Upstanding finger ring 60 provides good ergonomic characteristics, which isolate the needle withdrawal traction forces that may be resisted by the finger in ring 60 from the needed pressure on the overlying gauze by other fingers, as the needle is being withdrawn from the patient, to provide hemostasis.

Apart from that, sheath 10b can be of identical design, and can work in a manner identical to, the sheaths of the previous embodiments. Note that the needle 56a may be placed into the sheath 18a with a point inverted from the position of needle point 56. Either position is suitable for these sheaths.

Referring to Fig. 6, another embodiment of sheath 10c may be of similar structure and function to the previous sheaths except as otherwise described herein. The end wall 48c at the second end of sheath 10c partly but not completely blocks the bore extending through the hollow sheath 10c, to serve as a structure equivalent to end walls 48, 48a for similar purposes of holding the rotational orientation of a needle and hub 50 captured within the sheath. As one difference, end wall 48c may

be an angled straight wall, rather than a curved wall as in the previous embodiments, extending down to bottom position 54c.

At the other end of the sheath 10c, the  
5 upstanding handle for manual retention 60c comprises a partial arc attached to the rest of sheath 10c at only one end, as shown. This structure is also suitable for being gripped with one finger to hold sheath 10c in its desired position as the needle is being pulled out of  
10 the patient and into retracted relation within the sheath 10c.

Upstanding handle members 60, 60c have widths preferably substantially identical to the widths of sheaths 10b, 10c in a manner similar to that generally  
15 indicated in Fig. 3, although other widths may be used if desired.

Thus, a sheath for winged medical needles is provided, in which the needle may be comfortably and reliably pulled from the patient while the sheath is  
20 manually retained with a finger, and the wings slip into the respective slots 22, to encourage the needle to withdraw from the patients' skin at a shallow angle which approximates the axis of the needle in the skin. This reduces pain. Then, as the needle wings are being  
25 withdrawn through slots 22 and enter into the second slot section 32, the needle can spontaneously rotate through a small angle so that the wings become more parallel to the direction of first slot section 40 which extends at a different angle. The needle is thus  
30 rotated upwardly so that its tip can press against the lower surface of the upper wall 12, being held there so that the needle cannot accidentally pass through one of

the slots to the exterior.

Referring to Figs. 7-9 drawings, medical needle protector sheath 100 is shown to be carried on tubing 120 of a conventional winged needle fistula set 140, having a needle 16, closed with a removable needle guard 180,, and having wings 200 projecting outwardly from hub 170. The tubing 120 can be seen to be extending entirely through the hollow interior of protector sheath 100.

Protector sheath 100 comprises a body having a top wall 220, sidewalls 240, and a slot 260 formed in each sidewall to receive a needle wing 200 as the needle is retracted from the patient rearwardly into protector sheath 100 and held there by latching of the wings.

The respective slots 260 define first slot portions 280, each of the first slot portions having one closed end 290 adjacent one end 300 of the body of sheath 100.

The respective sidewalls 240 each define a catch projection 320, each of which is spaced from the respective closed end 290 of slot portion 280, and which serves to prevent needle wings that occupy first slot portions 280 from easily sliding away from the first slot portions. Catch projections 320 are also sufficiently flexible, as particularly shown in Fig. 8, to be deflected downwardly as the respective needle wings 200 slide from the open mouth 340 of slots 260, along the slots, to enter the first slot portions 280 by deflection of catch projections 320 as in Fig. 8. Then, as shown in Fig. 9, catch projections 320 can spring back into their original configuration in which a wing catching tip 330 of the catch projection 320 is either

in contact with the upper surface 360 of slot 280 or in close proximity thereto, less than the thickness of the wings 200. Thus, as Fig. 9 illustrates, the respective wings 200 are not easily removed from their occupancy of the first slot portions 280 once they have entered the first slot portions. Thus, the sharp point of needle 160 is also retained within the protector sheath, typically being pressed against the underside of top wall 220 because the first slot portions 280 extend at an acute angle away from top wall 220 from the vicinity of elongated members 320 to the closed ends 290, as shown in phantom lines 160 in Fig. 9. Typically this acute angle is about 5 to 20 degrees. Also, end wall 400 presses tube 120 to help hold needle 160 up to engage the top wall 220.

Elongated member 320 may carry a longitudinal strengthening rib 330.

Sheath 100 also comprises a bottom wall 380 and an end wall 400 at and adjacent the one body end 300. End wall 400 extends from the vicinity of top wall 220 downwardly in an angled manner to a position above bottom wall 380, so that an aperture 420 is provided in a lower portion of the sheath, through which tubing 120 can extend. However, as shown particularly in Fig. 7, tubing 12 is thus forced downwardly by end wall 400, away from top wall 220, which, in turn, facilitates the forcing of the needle 160 to upwardly rotate at flexible wings 200, to assure an upward position of needle 160 as shown in Fig. 9 so that the sharp point is well out of harm's way, and also to prevent the sharp needle point from accidentally projecting outwardly through one of slots 260.

The remaining portions 440 of slots 260, which are more remotely spaced from end wall 290 than elongated member 320, may extend from the vicinity of elongated member 320 in an acute angle away from top wall 220 to the open slot ends 340. Typically, this acute angle is also about 5 to 20 degrees, as is the corresponding acute angle of first slot portion 280.

At the end of the sheath which is opposed to first end 300, an integral, flexible, upstanding handle 460 may be carried, for manual retention of the sheath. The flexibility of handle 460 may be enhanced by the presence of a transverse line of flexing weakness 480.

The medical needle protector sheath of this invention may comprise a single, integrally molded piece made of a plastic which is somewhat flexible at the dimensions used. Thus, as previously described, the sheath can be used with winged needles in which the wings 20 are spaced from the longitudinal axis of the set as defined by the axis of needle 16 irrespective of whether the needle and set are in use with the bevelled tip 50 facing downwardly as shown in Fig. 7 or in an inverted position where the bevelled tip 50 faces upwardly. The flexibility of sheath 100 can accommodate the differing dimensions or location of the wings in these two circumstances because of the design of the elongated member 320 of the catch projection, as shown. The front surface 520 of elongated member 320 is angled slightly forwardly from bottom to top so that when wing 200 is attempted to be retracted along the slots toward their mouths 340, the elongated member 320 of the catch projection is forced upwardly by the wing to engage the upper wall 360 of slot portion 280. Thus, no amount of

pulling, apart from destruction, can cause wings 200 to be dislodged out of their locked position, and this situation continues to hold even when the sheath is twisted, opened, or otherwise manually deformed.

5                   Accordingly, as taught in Utterberg U.S. Patent No. 5,112,311, the fistula needle 160 is positioned in the vein of a patient, and the wings are strapped to the skin. For removal of the fistula needle, the wings are released from their adhesive tape straps; a wad of gauze  
10 is placed on the puncture site of the needle to the skin; and the nurse presses the gauze on that point while hooking one finger around upstanding handle 460. Then, the nurse simply pulls on tubing 120 to withdraw needle 160, causing the needle and wings to retract back  
15 into protector sheath 100, with the wings 200 sliding through slots 260. The acute angle of slot 260 is present to match the approximate angle of needle 16 to the skin of the patient, so that the needle is not twisted as it is withdrawn. Then, as the needle  
20 continues to be withdrawn, sliding through slots 260, the wings 200 depress elongated member 320 of the catch projection, permitting the wings to slide into first slot portions 280. When the wings arrive in first slot portions 280, catch projections 320 spring back to their  
25 original position, as shown in Fig. 9, firmly and reliably retaining wings 200 in the position of occupying first slot portion 280. Simultaneously, since first slot portion 280 occupies an acute angle of opposite sense to the acute angle of the rest of slot  
30 260, and also because of the presence of wall 400 that forces tube 120 downwardly, needle 160 is forced to rotate upwardly so that the tip impacts against the

lower surface of wall 220, where it is firmly held out of harm's way.

The above has been offered for illustrative purposes only, and is not to be construed as limiting  
5 the scope of the invention of this application, which is as defined in the claims below.

## THAT WHICH IS CLAIMED:

1. A medical needle protector sheath which comprises a body having a top wall, side walls, and open  
5 first end, and a slot formed in each side wall to receive a needle hub wing extending through each of said slots;

said slots extending from said first end toward a second end opposed to said first end, said slots  
10 terminating in said side walls at end points spaced from said second end, said protector sheath also having an end wall defined at said second end, said end wall extending from the vicinity of said top wall downwardly to a position above the lower edges of said side walls,  
15 whereby said needle and hub may be held in the sheath at an acute angle to said top wall by means of abutment with a lower edge of said end wall, with a needle of said needle and hub pointing toward said top wall.

20 2. The protector sheath of Claim 1 in which first portions of said slots adjacent to said end points slope away from said top wall as said slots extend toward said second end.

25 3. A protector sheath of Claim 2 in which second portions of said slots, positioned adjacent to said first slot portions and nearer to said first end than said first slot portions, define a greater slot width than other slot portions to permit a degree of free  
30 vertical rotation of wings of a medical needle occupying said second slot portion.



4. The protector sheath of Claim 2 in which at least most of the length of said slots positioned between said first slot portion and the first end slope toward said top wall as said slots extend toward said second end.

5. A needle protector of Claim 1 in which a bottom wall is provided in a position connected to the lower edges of said side walls, said bottom wall being spaced inwardly from said second end to define a recess to permit a needle and hub positioned in said sheath to be tilted so that the needle tip engages said top wall and the hub occupies at least some of said recess.

6. The protector sheath of Claim 1 in which said first slot portions adjacent to said end points define first catch projections to prevent needle wings that occupy said slot portions from easily sliding back towards said first slot end.

7. The protector sheath of Claim 1 in which an upstanding handle for manual retention of said sheath projects from said top wall adjacent said first end.

8. A medical needle protector sheath which comprises a body having a top wall, side walls, an open first end, and a slot formed in each side wall to receive a needle wing extending through each of said slots; said slots extending from said first end toward a second sheath end opposed to said first end, said slots terminating in said sidewalls at end points spaced from said second end, first portions of said slots

adjacent to said end points sloping away from said top wall as said slots extend toward said second end; said protector sheath further comprising a bottom wall connected to said sidewalls, said bottom wall being  
5 spaced inwardly from said second end to define a recess to permit a needle and hub positioned in said sheath to be tilted so that the needle tip engages said top wall and the hub occupies at least some of said recess.

10 9. The protector sheath of Claim 8 in which an end wall is defined at said second end, said end wall extending from the vicinity of said top wall downwardly to a position above said bottom wall, whereby said needle and hub may be held in the sheath by abutment of  
15 said end wall at an acute angle to said top wall.

10. The protector sheath in Claim 9 in which said sidewalls adjacent to said end points define first catch projections at said first slot portions to prevent  
20 needle wings that occupy said slot portions from easily sliding back toward said first slot end.

11. The protector sheath of Claim 10 in which second portions of said slots, positioned adjacent to  
25 said first portions and nearer to the first end than said first portions, define a greater slot width than other slot portions to permit a degree of free, vertical rotation of wings of a medical needle occupying said second slot portions.

30

12. The protector sheath of Claim 11 in which at

least most of the lengths of said slots positioned between said first slot portion and the first end slope toward said top wall as said slots extend toward said second end.

5

13. The protector sheath of Claim 12 in which an outwardly extending handle for manual retention of said sheath projects from said top wall adjacent said first end.

10

14. The protector sheath of Claim 12 in which said top wall has a portion which extends forwardly beyond the sidewalls at said first end, and carries an upstanding handle.

15

15. The protector sheath of Claim 12 in which said top wall defines an elevated portion adjacent said first end, to permit greater use of the sheath with needles of different lengths.

20

16. A medical needle protector sheath which comprises a body having a top wall, side walls, an open first end, and a slot formed in each side wall to receive a needle hub wing extending through each of said slots;

25

said slots extending from said first end towards a second sheath end opposed to said first end, said slots terminating in said side walls at end points spaced from said second end, first portions of said slots adjacent to said end point sloping away from said top wall as said slots extend towards said second end, at least most of the length of said slots positioned

30

between said first slot portion and the first end sloping toward said top wall as said slots extend towards said second end;

5       said slots defining second portions, positioned adjacent to said first portions and nearer to the first end than said first portions, said second portions defining a greater slot width than other slot portions to permit a degree of free vertical rotation of wings of a medical needle occupying said second slot portions.

10

17.   The protector sheath of Claim 16 which further comprises a bottom wall connected to said side walls, said bottom wall being spaced inwardly from said second end to define a recess to permit a needle and hub  
15   positioned in said sheath to be tilted so that the needle tip engages said top wall and the hub occupies at least some of said recess.

18.   The protector sheath of Claim 16 in which an  
20   upstanding handle is provided for manual retention of said sheath of said top wall at or near said first end.

19.   A medical needle protector sheath which comprises a body having a top wall, sidewalls, a slot  
25   formed in each sidewall to receive a needle wing extending through each of said slots, and at least partially open ends, said slots each defining first slot portions, each having one closed end adjacent one end of said body and said first slot portions, said sidewalls  
30   defining at least one catch projection spaced from said closed ends to prevent needle wings that occupy said first slot portions from easily sliding away from said

first slot portions, said catch projection defining an elongated member having a first end that defines a wing catching tip extending into one of said slots, said elongated member being attached to the sidewall only at  
5 an elongated member end that is opposed to said first end, to permit said elongated member to flex in the sidewall plane, and further in which said elongated member extends in a direction that defines an acute angle to at least the majority of said top wall, with  
10 the first end of the elongated member facing said first slot portion.

20. The sheath of Claim 19 in which said first slot portions extend at an acute angle away from said  
15 top wall from the vicinity of said elongated members to said closed ends.

21. The sheath of Claim 20 which further comprises a bottom wall, and an end wall at the one body  
20 end adjacent said slot closed end portions, said end wall extending from the vicinity of said top wall downwardly to a position above the bottom wall, whereby said needle and hub may be held by abutment with said  
25 end wall in the sheath at an acute angle to said top wall when the wings occupy the first slot portions.

22. The sheath of Claim 21 in which said end wall extends diagonally outward from said top wall.

30 23. The sheath of Claim 21 in which portions of said slots which are more remotely spaced from said end wall than said elongated member extend from the vicinity

of said elongated member in an acute angle away from said top wall to open slot ends at the needle protector sheath end which is opposed to said one end.

5           24. The sheath of Claim 19 in which a flexible, upstanding handle for manual retention of said sheath projects from said top wall adjacent the end of said sheath which is opposed to said one end.

10           25. The sheath of Claim 24 in which said handle is substantially of C-shape.

15           26. The sheath of Claim 25 in which said handle communicates with said top wall through a line of flexing weakness to facilitate the flexibility of said handle, whereby the user, while withdrawing a winged needle into the sheath, may hold the upstanding handle with a finger, and the handle has sufficient stiffness to permit the needle to be pulled into the sheath and  
20           locked therein, but the handle is sufficiently flexible so that the sheath may be removed from the finger that the handle engages by flexing without a need to move the finger.

25           27. The sheath of Claim 19, which is made of a flexible plastic, to receive and hold winged needles of a variety of shape configurations.

30           28. The sheath of Claim 19, in which the wing catching tip extends toward a top wall of said slot, to be in contact with said top wall or spaced therefrom by a distance which is less than the thickness of needle

wings occupying said first slot portions.

29. The sheath of Claim 28, in which said elongated member carries a longitudinal strengthening  
5 rib.

30. A medical needle protector which comprises a body having a top wall, sidewalls, a slot formed in each sidewall to receive a needle wing extending through  
10 each of said slots, and at least partially open ends, said slots each defining first slot portions, each first slot portion having one closed end adjacent one end of said body, said sidewalls defining at least one catch projection spaced from said closed ends to prevent  
15 needle wings that occupy said first slot portions from easily sliding away from said first slot portions, said catch projection defining an elongated member having a first end that defines a wing catching tip extending into one of said slots, said elongated member being  
20 attached to the sidewall only at an elongated member end that is opposed to said elongated member first end, to permit said elongated member to flex in the sidewall plane, said sheath further comprising a bottom wall, and an end wall at said one body end adjacent said slot  
25 closed ends, said end wall extending from the vicinity of said top wall downwardly to a position above the

bottom wall, whereby said needle and hub may be held by said end wall in the sheath at an acute angle to said top wall when the wings occupy said first slot portions.

5           31. The sheath of Claim 30 in which said first slot portions extend at an acute angle away from said top wall from the vicinity of said elongated member to said slot closed ends.

10           32. The sheath of Claim 31 in which portions of said slots which are more remotely spaced from said end wall than said elongated member extend from the vicinity of said elongated member in an acute angle away from said top wall to open slot ends at the needle protector  
15 sheath end which is opposed to said one end.

          33. The sheath of Claim 32 in which a flexible, upstanding handle for manual retention of said sheath projects from the top wall adjacent to the end of said  
20 sheath which is opposed to said one end.

          34. The sheath of Claim 33 in which said handle is substantially C-shaped.



35. The sheath of Claim 33 in which said handle communicates with said top wall through a line of flexing weakness to facilitate flexibility of said handle, whereby the user, while withdrawing a winged  
5 needle into the sheath, may hold the upstanding handle with a finger, and the handle has sufficient stiffness to permit the needle to be pulled into the sheath and locked therein, but the handle is sufficiently flexible so that the sheath may be removed from the finger that  
10 the handle disengages by flexing without a need to substantially move the finger.

36. The sheath of Claim 33 which is made of a flexible plastic, to receive and hold winged needles of  
15 a variety of shape configurations.

37. The sheath of Claim 36 in which the wing catching tip extends towards a top wall of said slot, to be in contact with said top wall or spaced therefrom by  
20 a distance which is less than the thickness of needle wings occupying said first slot portions.

38. The sheath of Claim 37 in which said elongated member extends in the direction that defines

an acute angle to at least the majority of said top wall, with the first end facing said first slot portion.

39. A medical needle protector sheath which  
5 comprises a body having a top wall, sidewalls, a slot  
formed in each sidewall to receive a needle wing  
extending through each of said slots, and at least  
partially open ends, said slots each defining first slot  
portions having one closed end adjacent one end of said  
10 body, said sidewalls defining at least one catch  
projection spaced from said closed ends to prevent  
needle wings that occupy said first slot portions from  
easily sliding away from said first slot portions, said  
catch projection defining an elongated member having a  
15 first end that defines a wing catching tip extending  
into one of said slots, said elongated member being  
attached to the sidewall only at an elongated member end  
that is opposed to said first end, to permit said  
elongated member to flex in the sidewall plane, said  
20 elongated member also extending in a direction that  
defines an acute angle to at least the majority of said  
top wall, with the first end facing said first slot  
portion, said first slot portions also extending at an  
acute angle away from said top wall from the vicinity of

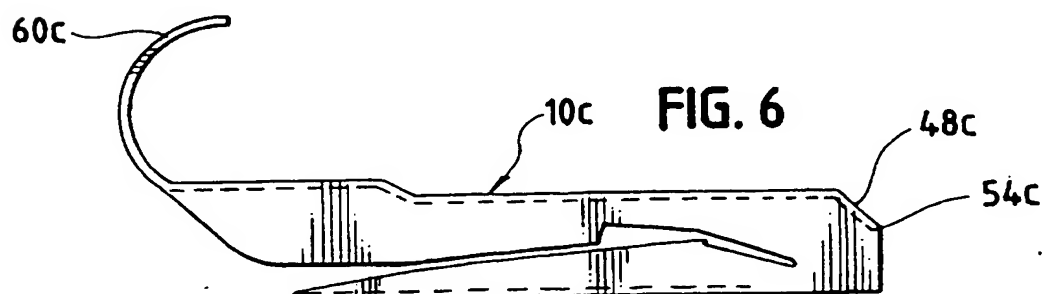
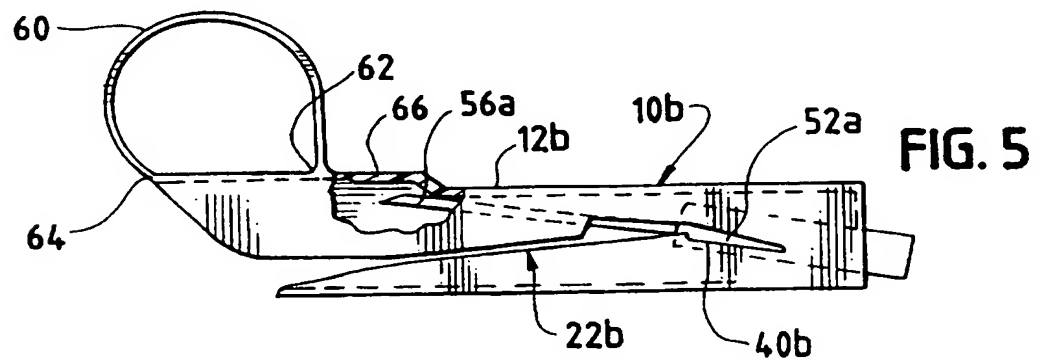
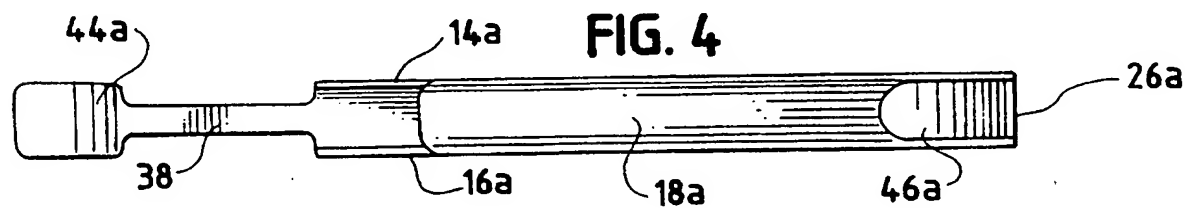
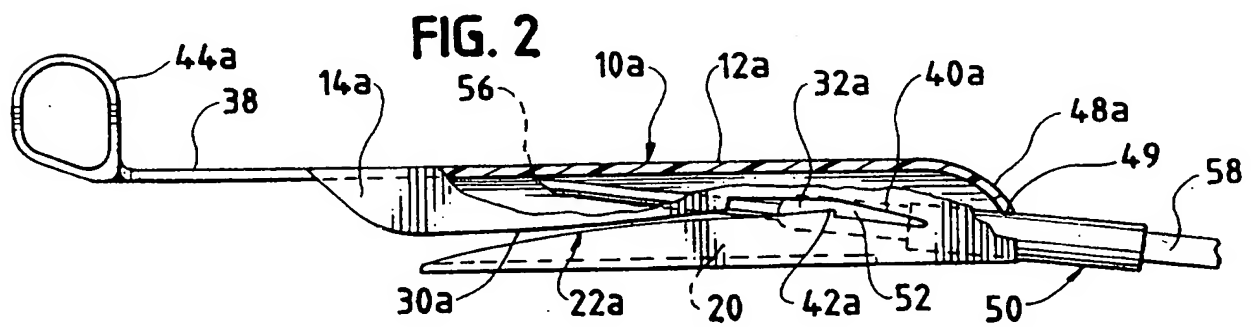
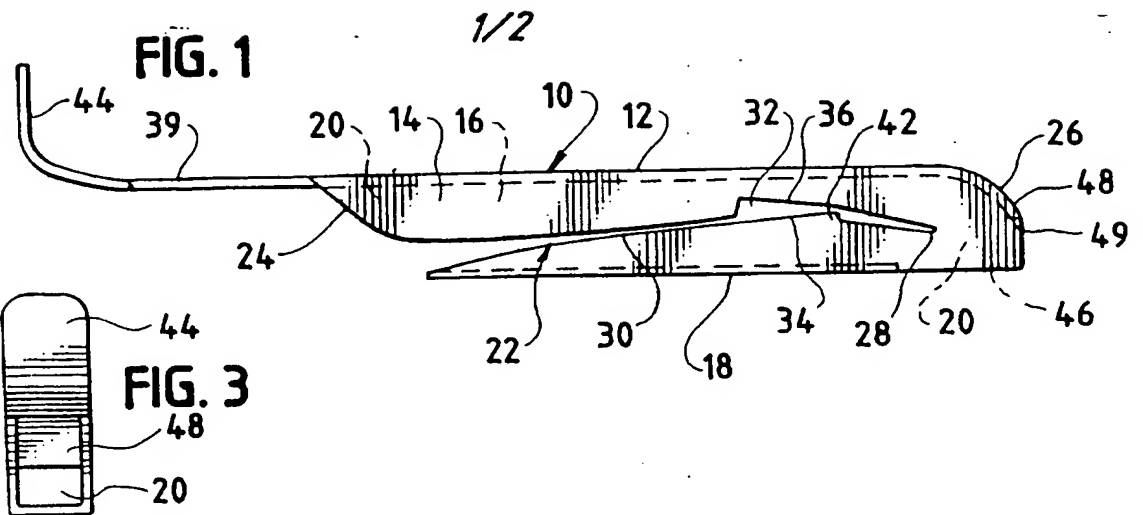
said elongated members to said closed ends, portions of said slots which are more remotely spaced from said closed ends than said elongated member extending from the vicinity of said elongated member in an acute angle away from said top wall to open slot ends at the needle protector sheath end which is opposed to said one end.

40. The sheath of Claim 39 in which a flexible, upstanding handle for manual retention of said sheath projects from said top wall adjacent the end of said sheath which is opposed said one end.

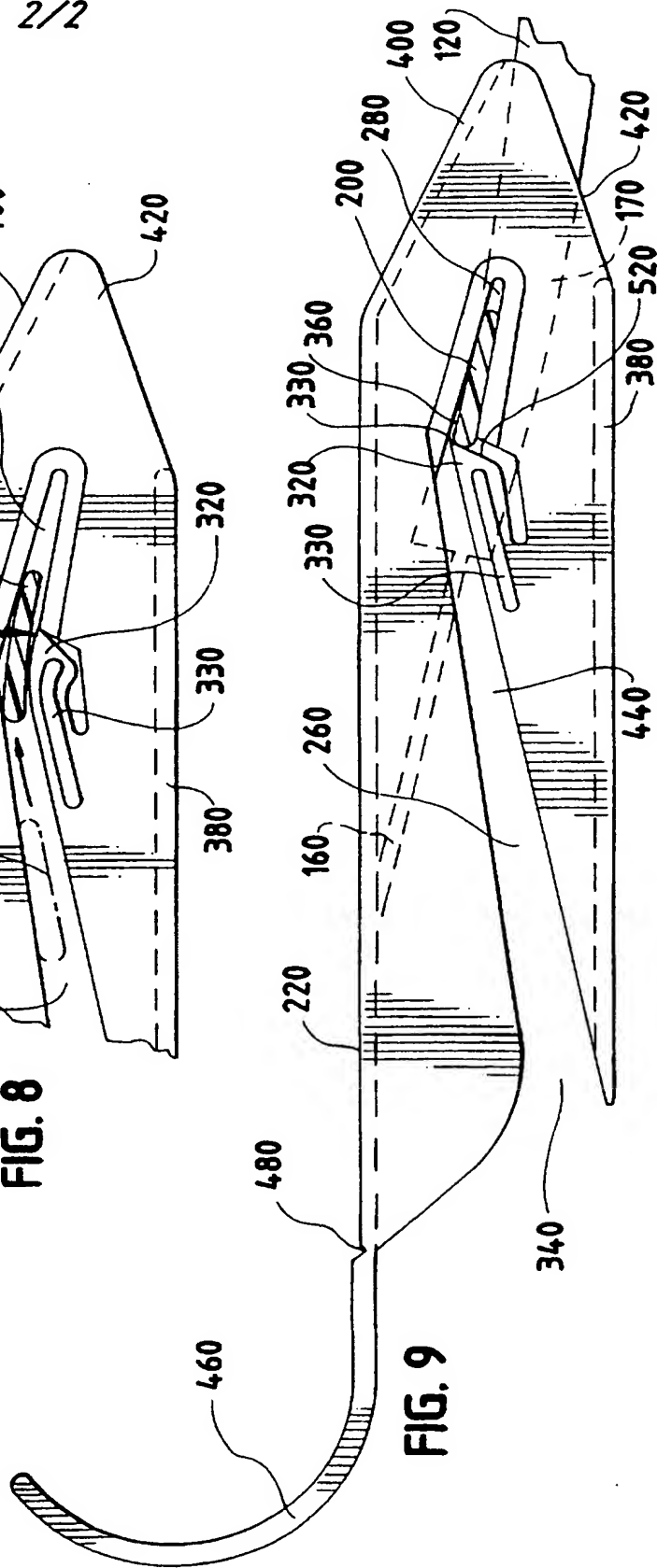
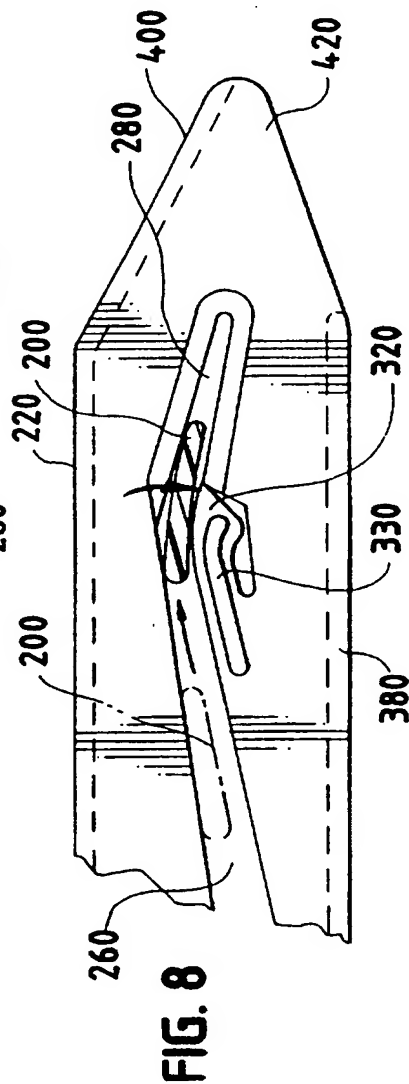
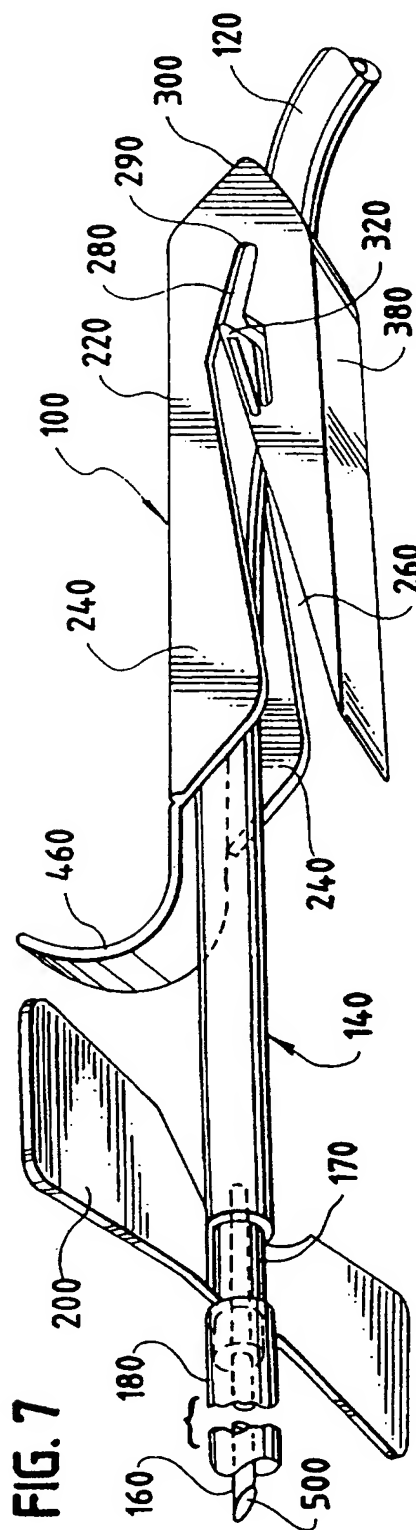
41. The sheath of Claim 40 in which said upstanding handle is substantially C-shaped, said handle having sufficient flexibility and strength whereby the user, while withdrawing a winged needle into the sheath, may hold the upstanding handle with a finger, and the handle has sufficient stiffness to permit the needle to be pulled into the sheath and locked therein, but the handle is sufficiently flexible so that the sheath may be removed from the finger that the handle engages by flexing without a need to substantially move a finger.

42. The sheath of Claim 41 which is made of a

flexible plastic, to receive and hold winged needles of a variety of shape configurations.



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# INTERNATIONAL SEARCH REPORT

International application No.  
PCT/US96/20740

## A. CLASSIFICATION OF SUBJECT MATTER

IPC(6) : A 61 M 5/00, 5/32

US CL : 604/171, 177, 198, 263

According to International Patent Classification (IPC) or to both national classification and IPC

## B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

U.S. : 128/912, 919, DIG. 26; 604/110, 162, 163, 171, 174, 177, 192, 197-199, 263

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

## C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 5,433,703 A (UTTERBERG et al) 18 July 1995, col. 12, line 27 to col. 13, line 15.	1-19, 24, 27, 30
X,P ----- Y,P	US 5,562,637 A (UTTERBERG) 08 October 1996, col. 5, line 35 to col. 7, line 13.	1-21, 23, 24, 30-33, 39, 40 ----- 22, 27, 36
Y	US 5,350,368 A (SHIELDS) 27 September 1994, col. 2, line 56 to col. 3, line 46.	22
A	US 4,935,011 A (HOGAN) 19 June 1990.	1
A	US 5,092,461 A (ADAM) 03 March 1992.	1
A	US 5,171,231 A (HEILIGER) 15 December 1992.	1



Further documents are listed in the continuation of Box C.



See patent family annex.

* Special categories of cited documents:	T	later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
*A* document defining the general state of the art which is not considered to be of particular relevance	X*	document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
*B* earlier document published on or after the international filing date	Y*	document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art
*L* document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)	A*	document member of the same patent family
*O* document referring to an oral disclosure, use, exhibition or other means		
*P* document published prior to the international filing date but later than the priority date claimed		

Date of the actual completion of the international search

25 MARCH 1997

Date of mailing of the international search report

16 APR 1997

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